

Drinking Water Laboratory Certification Program Guidance Manual

New Mexico Environment Department Drinking Water Bureau

Prepared by:
Diane Van Hoy, Quality Assurance Coordinato
Reviewed by: Bethany Anderson, Certification Authority
Approved by:
Ine Martinez Drinking Water Rureau Chief

Revision History Table

Revision #	Revision Date	Revised By	Reason for Revision
3.0	1/1/2020	Bethany Anderson	Annual Revision
4.0	11/1/2021	Diane Van Hoy	Annual Revision

Table of Contents

Acronyms	2
Acronyms I. Definitions and Descriptions	3
II. Purpose	4
III. Authority	5
IV. Organization	
V. Certification Types	6
VI. Certification Application	7
VII. Reporting Requirements	10
VIII. Certificate	
IX. Maintaining Certification	12
X. Certification Downgrading	16
XI. Certification Denial and Revocation	
XII. Upgrading or Reinstatement of Certification	19
XIII. Certification Evaluation	
XIV. Requirements for QAP	23
XV. Laboratory Ethics and Fraud Detection/Deterrence	26

Appendices

- Appendix A. Drinking Water Laboratory Certification Program Application
- Appendix B. DWLCP Checklist for Certification Application
- Appendix C. Drinking Water Laboratory Certification Program Best Practices
- Appendix D. Drinking Water Laboratory Certification Program Acknowledgment Form
- Appendix E. Subcontracted Laboratory (sub-lab) Request Form
- Appendix F. Quarterly Quality Assurance Report for Microbiological and Chemical Laboratories
- Appendix G. Corrective Action Response for Audit Findings (Micro Labs Only)
- Appendix H. Examples of Microbiological and Chemical Lab Chain-of-Custody Forms
- Appendix I. Instructions to Register for SDWIS LabToState
- Appendix J. Corrective Action Response for PT Study Failure (Micro Labs Only)
- Appendix K. Revised Total Coliform Rule Sample Reporting and Notification (LabToState)

Acronyms

A2LA: American Association for Laboratory Accreditation

ANAB: ANSI-ASQ National Accreditation Board ANSI: American National Standards Institute

ASQ: American Society for Quality

CA: Certification Authority

CFR: Code of Federal Regulations

CM: Certification Manager CO: Certification Officer COC: Chain-of-Custody DL: Detection Limit

DOH: Department of Health DWB: Drinking Water Bureau

DWLCP: Drinking Water Lab Certification Program

EPA: Environmental Protection Agency

HM: Heavy Metals

ISO\IEC: Internal Organization for Standardization/International Electrotechnical Commission

MCL: Maximum Contaminant Level MDL: Method Detection Limit

MPA: Microscopic Particulate Analysis MRL: Minimum Reporting Limit

NELAC: National Environmental Laboratory Accreditation Conference NELAP: National Environmental Laboratory Accreditation Program

NM: New Mexico

NMAC: New Mexico Administrative Code

NMED: New Mexico Environment Department

OSHA: Occupational Safety and Health Administration

PAA: Primary Accrediting Authority

PT: Proficiency Test QA: Quality Assurance

QAM/QAP: Quality Assurance Manual/Quality Assurance Plan

QC: Quality Control RAD: Radiologicals

SDWA: Safe Drinking Water Act

SDWIS: Safe Drinking Water Information System

SLD: Scientific Laboratory Division SOC: Synthetic Organic Compound SOP: Standard Operating Procedure SUVA: Specific Ultraviolet Absorption

TOC: Total Organic Carbon TNI: The NELAC Institute

VOC: Volatile Organic Compound WCF: Water Conservation Fund

Guidance Manual for Drinking Water Laboratory Certification Program

I. Definitions and Descriptions:

NOTE: Laboratories are responsible for tracking and meeting all required certification deadlines. DWB may not provide reminder notifications.

- B. <u>Audit</u>: A thorough review of labs processes, written procedures, personnel qualifications, data, etc. done to ensure that a lab is following all applicable rules and regulations.
- C. <u>Audit Report</u>: Report of findings made upon the completion of onsite audit.
- D. <u>Contract/Price Agreement</u>: An agreement between the lab and DWB stating which compliance sample analyses are paid by the Water Conservation Fund (WCF).

<u>NOTE</u>: Only labs certified by the NMED Drinking Water Laboratory Certification Program (DWLCP) are eligible to bid for DWB contracts to analyze drinking water samples for determining compliance with the SDWA and NM drinking water regulations.

- E. <u>Corrective Action Report</u>: Written report of action(s) taken to correct a problem related to a failure either found during an audit or failure of a Proficiency Test (PT) study. This is for chemical labs only.
- F. <u>Corrective Action Response</u>: forms used by microbiological labs to address a PT study failure or Department of Health audit finding. Templates for the forms can be found in Appendix G for audit findings and Appendix J for PT study failures.
- F. <u>Primary State Lab</u>: The EPA certified lab required as a condition of primary enforcement responsibility (primacy), 40 CFR § 142.10(b)(4). The current Primary State Lab for NM is The Department of Health Scientific Laboratory Division (SLD).
- G. <u>Proficiency Test Study</u>: Means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an accredited proficiency test provider. For more on PT study requirements see Section IX.
- H. Quality Assurance Manual/Plan (in this document referred to as the QAP): All certified laboratories are required to have a documented QAP. The QAP details the lab's QA/QC procedures including planning, implementation, and assessment used to ensure that routinely generated analytical data

are scientifically valid and defensible and are of known and acceptable precision and accuracy. For more on QAP including requirements elements of a QAP see Section XIV.

I. <u>Safe Drinking Water Information System (SDWIS)</u>: Analytical data must be electronically uploaded to SDWIS, or the current database of record. SDWIS is the Environmental Protection Agency's (EPA) database for tracking drinking water quality data and violations at public water systems. It is intended to help public water systems meet the reporting requirements of the Safe Drinking Water Act (SDWA). SDWIS ensures that compliance data may be shared quickly and accurately; internally, and externally. For more on SDWIS and data reporting requirements see Section VII below.

For instructions on how to sign up for DWB's SDWIS application known as LabToState see Appendix I. If the lab needs assistance with registration, please contact the DWB data steward in charge of registration. The current DWB data steward can be reached at Daniel.ramirez1@state.nm.us. This does not apply for Microscopic Particulate Analysis (MPA) labs.

J. <u>Standard Operating Procedure (SOP)</u>: A document that outlines the steps, equipment, quality control etc. for a routinely preformed procedure. SOPs can be for administrative or analytical tasks and are separate documents from the QAP.

II. Purpose:

The mission of the New Mexico Environment Department (NMED) Drinking Water Laboratory Certification Program (DWLCP) is to ensure that comparable, consistent, and legally defensible drinking water quality compliance data are reported from public water systems in New Mexico (NM) as required by the Safe Drinking Water Act (SDWA), the Code of Federal Regulations (CFR) 40 § 141-143, and New Mexico Drinking Water Regulations 20.7.10 New Mexico Administrative Code (NMAC).

The specific program goals ensure that all laboratories certified to analyze drinking water in NM adhere to quality assurance procedures and meet all Environmental Protection Agency (EPA) standards throughout the analysis process, from sample collection through the reporting of data into the NM/EPA database of record at the time of upload, currently the Safe Drinking Water Information System (SDWIS). It is necessary that all public water system compliance data is reported to SDWIS properly for the NMED Drinking Water Bureau (DWB) to assess and share data as required, and ultimately to protect public health in NM.

This program guidance document details the Drinking Water Laboratory Certification Program (DWLCP) process, organization, and requirements for certification in NM. The program is designed to meet the Environmental Protection Agency's primacy conditions (40 CFR § 142), the EPA Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5th Ed. (815-R-05 -004, January 2005) and all subsequent supplements; including Supplement 1 (EPA 815-F-08-006, June 2008) and Supplement 2 (EPA 815-F-12-006, November 2012), the National Environmental Laboratory Accreditation Program (NELAP) requirements as described in The National Environmental Laboratory Accreditation Conference (NELAC Standard), and the American Association for Laboratory Accreditation (A2LA) whose requirements are based upon the Internal Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 requirements for Testing/Calibration Laboratories.

III. Authority:

The regulations governing primacy require the establishment and maintenance of a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants including the designation by the State of a laboratory certification officer, or officers, certified by EPA, as the official(s) responsible for the State's certification program (40 CFR § 142.10(b)(3)(i)).

Federal Regulations require that analytical testing for compliance purposes be performed by certified laboratories (40 CFR § 141.28). The exceptions to this are tests for turbidity, free chlorine residual, temperature, pH, alkalinity, calcium, conductivity, orthophosphate, Total Organic Carbon (TOC), Specific Ultraviolet Absorption (SUVA), daily chlorite, and silica which may be performed by anyone acceptable to the state (EPA 815-R-05-004, January 2005). These analytes do not require auditing or PT studies.

The Department of Health Scientific Laboratory Division (SLD) is the Principal State Laboratory for drinking water in New Mexico and is certified by EPA to perform drinking water analyses. The DWB authorizes the SLD team of EPA certified Certification Officers (COs) to perform laboratory onsite audits for laboratories requesting certification from the DWLCP on a fee-for-service basis. The SLD audit report is submitted to DWB for inclusion in the certification evaluation.

The DWLCP only certifies laboratories analyzing samples by EPA approved drinking water methods. Only NM certified laboratories are eligible to bid for DWB contracts/price agreements to analyze drinking water samples for determining compliance with the SDWA and NM Drinking Water Regulations. Requests for other analyses or methods not identified or authorized for compliance under the EPA SDWA, 40 CFR 141-143 will not be considered.

DWB also accepts reciprocity certification applications from A2LA, NELAP, or EPA accredited drinking water laboratories.

IV. Organization:

The DWLCP meets the EPA requirements to maintain primacy by utilizing the expertise of the NM Principal State Laboratory, SLD, as DWB does not employ any full-time chemists or microbiologists. The DWLCP is maintained by the Certification Authority (CA), the Certification Manager (CM), and the Certification Officer (CO).

- A. CA: The DWB Water Conservation Fund (WCF) Manager also known as the CA is responsible for final review and certificate approvals, addressing laboratory issues, certification downgrades, and due process appeals. This position is not certified by EPA.
- B. CM: The DWB Quality Assurance Coordinator acts as the CM and is responsible for correspondence, application processing, and record keeping for all laboratory certifications. This position is not certified by EPA. The CM makes recommendations to the CA as whether the lab should be certified.
- C. CO: EPA certified QA personnel employed by SLD working with NMED under a third-party agreement. The CO reviews laboratory files, performs onsite audits (also referred to as assessments or evaluations), and recommends laboratories for certification based upon their findings. There are three types of COs: microbiological, inorganic, and organic. Currently only the microbiological CO is utilized by DWB.

NOTE: The recommendation from a CO is not the same as a certification under the NM DWLCP. The

findings of the CO are submitted to the CM who reviews the findings, along with the laboratory's application and supporting documents. The CM may then recommend that the CA certify the lab. **ONLY the CA can officially certify a lab.**

V. Certification:

- A. Laboratory Categories: There are three categories of laboratories certified through NMED DWLCP. A lab may certify in one or more categories.
 - <u>Chemical Labs</u>: Test for analytes including heavy metals, SOCs, VOCs, radiologicals, disinfection byproducts, etc. For a full list see appendix A. Certificates for chemical labs are currently only issued based on reciprocity.
 - Microbiological Labs: Test for the presence and/or quantity of total coliforms and E. coli.
 Microbiological labs typically have the NM DWLCP as their PAA; however, labs may also be certified through reciprocity.
 - 3. <u>Microscopic Particulate Analysis Labs</u>: Test for the presence and/or quantity of cryptosporidium and giardia. Certificates for MPA labs are currently only issued based on reciprocity.
- B. Certification Types: There are four types of certification in the NMED DWLCP.
 - 1. <u>Certified</u>: Laboratory meets the requirements of the current revision of the DWLCP Guidance Manual and all applicable regulatory requirements.
 - 2. Provisionally Certified: Laboratory has discrepancies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the National Primary Drinking Water Regulations (NPDWR) and within the policy required by their CA. A provisionally certified laboratory may analyze drinking water samples for compliance purposes if they notify their clients of this downgrade in writing and indicate this status on any analytical reports. Provisional certification may not be given if the CA believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.
 - 3. Interim Certification: May be granted in certain circumstances when it is impossible or unnecessary to perform an onsite audit. Interim certification status may be granted only when the CA judges that the laboratory has the appropriate instrumentation, is using the approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed the appropriate PT studies for the contaminants in question. A situation where this type of certification may be granted is for a laboratory that has requested certification for the analysis of additional analytes involving the use of a method for which it already has certification. The CA shall review the laboratory's quality control data before granting this type of certification. The CO must perform an onsite audit as soon as they are able.
 - 4. <u>Not Certified</u>: Laboratory that has major deficiencies and has not been able to demonstrate to the satisfaction of the CA the ability to produce consistently valid data.

VI. Certification Application:

In seeking NM drinking water certification, a laboratory begins the certification process by submitting the application found in Appendix A of this document.

An email notification of receipt will be provided for all applications submitted. If any additional information is needed to process the application the applicant will be notified within **45 days.**

- A. The application may be one of the following types:
 - 1. <u>New</u>: A request for the first-time certification for regulated chemical analytes or microbiological contaminants, or a request to re-certify after certification has expired.
 - 2. <u>Amendment</u>: A request for certification to analyze additional, or newly regulated contaminant groups.
 - 3. <u>Renewal</u>: A request to re-certify a current certification prior to expiration.
 - 4. Reciprocity: May be used in combination with one of the other three types of applications. Reciprocity certifications require the laboratory to be certified by a Primary Accrediting Authority (PAA). The PAA may be A2LA, EPA, or a program with NELAP credentials. The lab may also have Secondary Accrediting Authority, but this is not required.
- B. Required Application Documents:
 - 1. Appendix A (certification application) of this manual which includes:
 - i. The date the application is submitted.
 - ii. The type of application.
 - iii. The Legal Name, ID number, lab type, and contact information for the lab and the owner of the lab.
 - iv. The lab's primary and secondary accrediting authority (if not certified directly through the NM DWB), the primary/secondary certification expiration date.
 - v. The date of the lab's last onsite audit by the primary/secondary accrediting authority.
 - vi. Signatures of the Laboratory Director, QA Officer, and Laboratory Supervisors/Group Managers attesting to the fact that all personnel have the proper education and training.

NOTE: The QA Officer should not be the Laboratory Director and should be separate from the analytical group they are responsible for overseeing. The exception is for small labs that do not have sufficient personnel to separate these duties.

- vii. List of technical personnel including their position/title and the test methods they perform. The lab may add this as an additional page to the application if necessary.
- viii. The approved analytical methods requested for the analytes that the lab wishes to be certified for. Approved analytical methods are methods approved by the EPA under SDWA (40 CFR § 141.21-141.30, 141.40-42), NM Drinking Water Regulations 20.7.10 NMAC, EPA approved alternate analytical techniques as approved by the Certification Authority, or methods that appear on the NELAP certification and have passing PT results for drinking water. Requests for other analyses or methods not identified or authorized for compliance under the EPA SDWA, 40 CFR § 141 will not be considered or approved.

For Chemical labs approved analytical methods must appear on the scope of accreditation for the lab's primary certification and must be accompanied by passing proficiency test study results. Laboratories must ensure that methods used will produce results which meet the Detection Limit (DL) for each analyte as specified under 40 CFR § 141.2.54. Failure to use the correct methods or meet the DL may be grounds for downgrading, revoking, or denying certification status by the DWLCP.

The DWLCP requires that laboratories seek certification for groups of analytes as outlined under the SDWA (see 40 CFR § 141-National Primary Drinking Water Regulations, Subpart C-Monitoring and Analytical Requirements & 40 CFR § 143-National Secondary Drinking Water Regulations). Laboratories must be certified for all the analytes of a specific group covered under the rule. No partial certifications will be issued (See table in Appendix A).

For example, a lab must certify for all SOCs not just the ones analyzed by a specific method. The lab can pick and choose analytes such as dioxin or TOC listed under individual parameters. If a laboratory loses certification for a particular analyte, the whole group is removed from their certification. For example, if the lab loses certification for benzene, it loses certification for the entire VOC group.

- ix. Instrument list may make a reference to QAP or attach a separate document. Must include all major equipment (i.e., mass spectrometers, gas chromatographs, etc.) used for method(s) requested.
- x. Signatures acknowledging the requirements for PT studies.
- xi. Signatures that the lab has not made any false statements and they will follow all regulations including submittal of results through SDWIS.
- xii. Date that the lab demonstrated capability to upload data to SDWIS. This is done through a practice upload of test data. Analytical data does not have to be real results. This demonstration only needs to be performed once and it must be performed successfully for each analyte for which certification is requested. This must be completed prior to certification approval. (Not applicable to MPA laboratories.)

2. Copy of the lab's current primary/secondary certification including the scope of accreditation if certified by reciprocity.

3. Current resumes for the lab director, supervisors, and QA personnel listed on page 3 of the application.

4. Audit documentation

- i. For chemical/MPA labs this includes: the audit report, any corrective action reports requested by the auditor, documents that were attachments to the corrective action reports, and an audit closure letter (or some form of proof that the auditor is satisfied with the corrective action report and has officially closed the audit).
- ii. For microbiological labs this includes: the SLD audit report or proof that an audit has been scheduled. SLD will send the audit report directly to NMED if the audit report is not ready at the time of application. If there are any significant findings during the audit the lab must submit a separate corrective action response for each finding within 30 days of receiving the audit report. If the corrective action report does not address the findings or is not received within the thirty-day limit it may constitute grounds for downgrading, revoking, or denying certification status by the DWLCP. A template for this report can be found in Appendix G.
- 5. The labs most recent QAP.
- 6. Applicable Standard Operating Procedures (SOPs), i.e., SOPs for the requested analytical methods, log-in and tracking, and any relevant administrative SOPs for employee training, data processing and storage, support equipment calibration etc. referenced in the QAP. Also include a list of SOPs either in the QAP or as a separate document.

NOTE: The QAP and SOPs must have some form of approval signature and date. (Electronic signatures are acceptable.) They also must have a revision/version number. The QAP and all analytical method SOPs must be reviewed **annually** and should include a review/revision history table. Analytical SOPs must reference the EPA approved method used, for example Standard Methods 21st Edition method 9222B.

- 7. Last two sets of PT test results for all analytes/methods for which certification is being requested. Laboratories adding new analytes or analyses must submit at least two successful sets of PT sample results for analytes and methods for which certification is being requested.
- 8. A blank copy of the laboratory's Chain-of-Custody (COC) form(s). Laboratories must agree to accept a NM issued COC or obtain approval of their COC by the DWLCP. COCs must contain the necessary information required by SDWA regulations to successfully upload information into DWB's database of record at the time of upload. Example COCs can be found in Appendix H.
- 9. Annual Method Detection Limit (MDL) studies and the associated Minimum Reporting Levels (MRL), as applicable for each method and analyte for which they are seeking certification. This may be submitted as a spreadsheet. (Chemical labs only.)

10. Subcontracted Laboratory Request forms (Appendix E) for any labs the lab subcontracts with for NM samples.

C. Application Fees: At this time, there are no fees required for the application review and certification. However, the SLD onsite audits and required PT studies are at the expense of the laboratory. Accreditation services and/or secondary accrediting/certification authorities with which the laboratory chooses to do business will also levy additional fees on the laboratory.

VII. Reporting Requirements:

Failure to properly report or notify sample results may be grounds for downgrading or revoking certification status by the DWLCP.

- A. Laboratories must provide a copy of all sample results to the submitter/client within **ten working days** from the completion of the analyses.
- B. Results obtained from a subcontracted laboratory must indicate their NM laboratory ID# number (as listed in SDWIS) on the report. Primary laboratories must provide the COC from the subcontracted laboratory if requested by DWB staff. Laboratories are not permitted to subcontract out samples unless they have completed the DWLCP Subcontracted Laboratory Request Form and received approval from the CA.
- C. Electronic reports of analytical results and data elements must be provided in a format that will upload effectively into the SDWIS database, or current database of record in accordance with the terms and conditions specified by DWB.
 - Laboratories are required to maintain capability to upload data to the current database of record. Failure to maintain electronic data upload capabilities may be grounds for revocation of certification.

NOTE: Uploading of data must only be performed by the laboratory personnel listed in the DWLCP application, or as notified by the lab for personnel changes.

- 2. If the DWB database is upgraded or changed to meet requirements set forth by DWB or EPA, the laboratory will be provided training or instructions by DWB on how to modify the data elements as needed to complete an updated method of data transfer.
- D. Immediate notification within 12-24 hours, to the submitter/client is required for the following circumstances:
 - 1. Any Total Coliform (TC) or E. *coli* positive result (12 hours)
 - 2. Any organic sample result that is identified at the DL as specified under 40 CFR § 141.24(f)(11) or (h)(18) or greater (24 hours)
 - 3. Any inorganic sample result that is identified at ½ of the MCL as specified under 40 CFR § 141.23(a)(4)(i) or greater (24 hours)
 - 4. Any Radiological sample result that is identified at ½ of the MCL or greater as specified under 40 CFR § 141.66 (24 Hours)
 - 5. Any sample that is rejected by the laboratory for not meeting the submission criteria for which analysis is being requested (i.e. leaking, frozen, temperature exceedance, hold time exceedance,

- etc.) must be reported to the water system and the DWB, or EPA (or the EPA designate) (24 hours)
- 6. Any sample that will be reported by the laboratory as "laboratory accident" must be reported to the water system and the DWB, or EPA (or the EPA designate) (24 hours).
- E. A laboratory must keep a written record of contacts (known as a contact log) made to report results requiring immediate notification. The record must contain information identifying the sample collector, who was contacted (name and affiliation), when the contact was made (date and time), and how the contact was made (in person, by phone, or by e-mail). Failure to maintain a contact log may be grounds for downgrading or revoking certification status by the DWLCP.
- F. Chemical labs that are a subcontractor of a lab that is under contract/price agreement with the NMED DWB will submit results to the lab with the NMED DWB contract/price agreement. That lab will then upload the results into SDWIS. The lab under the NMED DWB contract/price agreement is also responsible for immediate notifications and contact logs.
- G. Microbiological laboratories shall follow the Revised Total Coliform Rule Sample and Reporting and Notification (LabtoState) instructions (Appendix K).

VIII. Certificate:

A. Certificate: Laboratories approved for certification in New Mexico will receive a certificate signed by the CA and it shall be considered an official document. It will be transmitted as a signed and dated (effective date and expiration date) document containing the NMED logo. The certificate shall include a separate document known as the scope of accreditation with the specific fields of testing, analytes, and methods for which the laboratory is certified. The lab will also receive a certification letter signed by the CM.

NOTE: Upon receipt of the certificate and scope of accreditation the laboratory should review the approved methods and expiration date of the documents. If any discrepancies are found notify the CA or CM immediately.

- B. Use of Certification: A certified laboratory shall not misrepresent its scope of accreditation or its status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations, or other materials. Such misrepresentation may result in certification suspension or revocation. If a certified laboratory wishes to change its scope of accreditation, the DWLCP must be notified so the scope may be reviewed and revised as appropriate. Upon approval, a new certificate will be issued detailing the parameters of the revised certification.
- C. Subcontracting and Suppliers: Laboratories subcontracting out samples to secondary laboratories for analyses must ensure secondary laboratories are certified by DWLCP as well as NELAP, A2LA, or EPA to perform those methods. The laboratory must submit a Subcontracted Laboratory Request form, which must be approved by the DWLCP CA. Unless DWLCP specifies a subcontractor the laboratory is responsible for ensuring the subcontractor's work is of appropriate quality. The laboratory shall keep a list of all subcontractors and proof of their accreditation with NELAP, A2LA or EPA.

NOTE: Microbiological laboratories certified by DWLCP may **NOT** subcontract any samples to a secondary laboratory.

The lab shall only use outside services and supplies of the necessary quality to ensure that lab results meet regulatory standards. The suppliers should meet NELAP or ISO/IEC 17025 standards. The lab shall keep a list of their suppliers and records of the evaluation of these suppliers. For requirements for reporting results from subcontractors see Section VII subsection F.

- D. Certificate Expiration Dates: The date a certificate expires depends on the certification category and whether lab is certified through reciprocity.
 - 1. If a lab in any certification category is certified through reciprocity the DWLCP certificate will have the same expiration date as the certificate issued by their primary accrediting body. The period for a reciprocity certification is generally one year.
 - 2. If a lab is categorized as a microbiological lab and **not certified** through reciprocity certificates are valid for up to **three years**. The date of expiration is based on the date of the labs first onsite audit.

IX. Maintaining Certification:

Failure to meet the requirements to maintain certification shall constitute grounds for downgrading or revocation of certification as described in Sections X and XI of this document.

- A. Microbiological Lab Document Requirements:
 - 1. Submit all documents list in Section VI at least 90 days prior to certification expiration date.
 - Submit current QAP, SOPs, and PT study results for the Annual QA Review. Documents should be submitted based on the month that the lab's certification expires. This is only done during years when the lab does not apply for certification renewal. For example, if a lab's certification expires in August 2024 the lab would submit documents for the Annual QA Review in August of 2022 and 2023.
 - 3. Submit QA reports (see Appendix F for a template) quarterly, which should include the following data:
 - i. Total number of sample results reported
 - ii. Total number of samples rejected (with reason for rejection noted on the report)
 - iii. Total number of lab errors (sample analyzed but results could not be reported)
 - iv. Total number of routine total coliform and E. coli positives reported
 - v. Percent of results reported within 10 days of analysis.

NOTE: Quarterly reports are due within **15 days** of the end of the quarter. For example, first quarter reports are due April 15th.

B. Chemical Lab Document Requirements:

- 1. Submit all documents list in Section VI (annually **90 days** prior to certification expiration date, which coincides with the expiration date of the laboratory's primary accreditation).
- 2. If the lab is under contract/price agreement with DWB it must submit a quarterly QA report (see Appendix F) for a template, which should include the following data:
 - i. Total number of sample results reported
 - ii. Total number of samples rejected (with reason for rejection noted on the report)
 - iii. Total number of lab errors (sample analyzed but results could not be reported)
 - iv. Percent of results reported within 10 days of analysis
 - v. Percent of results reported within 30 days of analysis
 - vi. Percent of results reported within 60 days of analysis
 - vii. Percent of results reported within 90 days of analysis.
- C. Audits: DWB authorizes the SLD EPA certified laboratory auditor(s) to perform onsite audits for laboratories requesting certification from the DWLCP on a fee-for-service basis. Onsite audits for labs certified through reciprocity may be performed by A2LA, EPA, or a NELAP approved accrediting body.

Audits are typically performed **every two years** for chemical labs and **every three years** for microbiological labs. Audits may also be performed when, the lab has a major change as described below, the lab repeatedly fails PT studies, or there are significant deficiencies such that follow up audits are required. These audits may be initiated by the CA, CO, or the laboratory. If initiated by the CA, the audit may be announced or unannounced and will be paid for by the DWLCP. Reasonable access to the facilities, equipment, and records must be granted to the auditors during regular working days and hours.

D. Proficiency Test (PT) Studies:

- 1. Requirements for PT Studies: To maintain certification, laboratories must continue to complete their PT studies in accordance with their PAA's requirements as well the requirements given below and ensure those results are provided to the DWLCP.
 - i. All certified laboratories must, at their own expense, analyze PT samples for each analyte and method for which they desire certification. PT studies must be analyzed at the frequency required by the laboratory's accrediting authority, but in no case less frequent than annually.

NOTE: Microbiological labs whose primacy certification is through DWB must provide one set of passing PT studies annually, based upon the calendar year.

ii. If a laboratory wishes to be certified for a contaminant by more than one method, it must analyze the PT samples by each method for which it wishes to be certified (40 CFR § 141.23(k)(3)(ii), 14I.24(h)(I 7)(i)(A) and 141.89(a)(I)(i)).

iii. The lab must have at least one passing PT study annually for each combination of method and analyte.

- iv. When analyzing a PT sample, a laboratory must use the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.
- v. The laboratory should be able to provide documentation to the CA that the person(s) analyzing PT samples is a laboratory employee who routinely analyzes drinking water compliance samples.
- vi. PT study must come from an accredited provider who sends the results directly to the DWLCP at NMENV-DWBlabcert@state.nm.us. The list below is an example of accredited providers from the NELAP website https://nelac-institute.org/content/NEPTP/ptproviders.php

•	Absolute Standards, Inc.	800-368-1131
•	Advanced Analytical Solutions, LLC	304-422-4274
•	Environmental Resource Associates, Inc.	303-431-8454
•	<u>MilliporeSigma</u>	307-742-5452
•	NYS DOH Wadsworth Center	518-474-7161
•	NSI Solutions, Inc.	800-234-7837
•	<u>Phenova</u>	303-940-0033

- vii. In addition to the required annual or semiannual PT studies labs may need to submit the following PTs:
 - Initial: A laboratory seeking to obtain accreditation must successfully complete two PT studies for each requested analyte/method. These two studies must have occurred within 18 months of the laboratory's application date and must be a minimum of 7 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing.
 - Supplemental: A laboratory participates in supplemental PT studies when the lab desires
 to add new fields of testing to their scope. Two supplemental tests are required.
 Analysis date of supplemental PT studies must be a minimum of 7 calendar days apart
 from the closing date of one study to the shipment date of another study for the same
 field of proficiency testing. Supplemental studies may also be necessary in the case of a
 PT study failure.

2. Evaluation of PT Studies:

i. All Labs: Quantitative data shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Acceptable results are those that are within the interval defined by the mean plus the or minus two standard deviations or with the 99% confidence limits as set by the mean, standard deviation, and set size (n) for their respective data for all other analytes.

ii. Microbiological Labs:

- Most Probable Number data should be transformed to logs prior to statistical analysis.
- Qualitative Analyses Participating laboratory results shall be considered "Acceptable" or "Unacceptable" when compared to the known presence or absence of total coliform or fecal coliform (E. coli) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.
- 3. Failure of PT Studies: May be grounds for downgrading, revoking, or denying certification status by the DWLCP. A lab is consider as having failed a PT study if:
 - i. They fail to meet the required schedules of the primary accreditation authority, whether annual or semiannual.
 - ii. Failure to analyze the PT sample within the acceptance limits specified in the regulations, or within the evaluation policy described above.

Chemical Labs shall correct failed PT studies in accordance with their PAA's requirements.

Microbiological labs that fail a PT study must notify the DWLCP immediately, determine the cause of the failure, and submit a Corrective Action Response for PT Study Failure form (Appendix J) to the CM within 30 days of the PT failure. The laboratory must also order a new PT study to verify they are still able to successfully analyze samples for compliance. Proof that an additional PT study has been ordered must be submitted with the Corrective Action Response. If a microbiological laboratory fails two consecutive studies, they must pass two consecutive studies to remain in compliance and must meet the requirements of the initial accreditation.

- E. Major Changes to the Lab: Failure to notify the CM of a major change that impacts or has the potential to significantly impact data quality may be grounds for downgrading or revoking certification status by the DWLCP.
 - 1. Change in personnel, equipment or location: Certified laboratories must notify the DWLCP by email, within 30 days of major changes in personnel, equipment, or laboratory location. A major change in personnel is defined as the loss or replacement of the laboratory supervisor, or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted. The CM should discuss the situation with the CA and laboratory management. A schedule should be provided for the laboratory to further address major changes. If the CA determines that the laboratory can no longer produce valid data, the CM should follow the procedure for revocation of certification.
 - 2. Change in ownership: Certification may be transferred when the legal status, ownership, or location of a certified laboratory changes without affecting its staff, equipment, or organization. Any change in ownership and/or location of a certified laboratory must be reported in writing to DWLCP within thirty (30) days of the change. The CA may require an onsite audit to verify impacts of such changes on laboratory performance.

For a change in ownership, the following conditions must be in effect:

i. The previous (transferring) owner must agree in writing, before the transfer of ownership takes place, to be accountable and liable for any analyses, data and reports generated up to the time of legal transfer of ownership; and

- ii. The buyer (transferee) must agree in writing to be accountable and liable for any analyses, data and reports generated after the legal transfer of ownership occurs.
- iii. All records and analyses performed pertaining to certification must be kept for a minimum of <u>5 years</u> and are subject to inspection by the accrediting authorities during this period without prior notification to the laboratory. This stipulation is applicable regardless of change in ownership, accountability, or liability.
- iv. If ownership is transferred, the transferee may not be responsible for payment of fees to the accrediting authorities during the remainder of the annual period, provided that the previous owner has fully paid the required fees, if any.

X. Certification Downgrading

- A. Criteria for Downgrading: A laboratory should be downgraded to "provisionally certified" status for an analyte or analyte group for any of the following reasons:
 - 1. Failure to analyze PT studies at least annually (or at an increased frequency as required by their primary accrediting body) for any analyte that is requested in Appendix A of the certification application.
 - For chemical labs failure of two consecutive PT studies for the same analyte and method.For microbiological labs failure of a single PT if the Corrective Action Response including proof that a new study has been ordered is not submitted within 30 days of the failure.
 - 3. Failure of a certified laboratory to notify the CM within 30 days of major changes (e.g., in personnel, equipment, or laboratory ownership/location).
 - 4. Failure to maintain the required standard of quality, based upon a[n] EPA (or other DWLCP approved) onsite evaluation.
 - 5. Failure to report or notify submitter/client (SDWIS database and hard copy) in a timely manner and in accordance with the requirements specified in Section IX Maintaining Certification, thereby preventing or delaying determination of compliance with Federal or State regulations and potentially endangering public health.
 - 6. Failure to respond to the CO and DWLCP within thirty (30) days of receiving an onsite audit report with findings/deviations (NM Microbiological Labs).
 - 7. Failure to analyze samples to the required DL as specified in 40 CFR § 141 for each analyte for which the laboratory is certified.
 - 8. Failure to implement the procedures and requirements of this Guidance Manual, as well as all requirements included in the Appendices.

- B. Procedures for Downgrading Certification not Based on a PT Study:
 - 1. The CA must notify the Laboratory Director, Quality Assurance Officer, or owner by emailing a signed pdf letter of its intent to downgrade within fourteen (14) days from becoming aware of the situation warranting downgrading. A hard copy of the letter is also mailed to the laboratory's business address of record.
 - 2. The laboratory official should review the problems cited and, within fourteen (14) days of receipt of the letter, send a written response to the CA specifying what immediate corrective actions are being taken, and any proposed actions that need the concurrence of the CA.
 - 3. The CA should consider the adequacy of the response and notify the laboratory in writing of its certification status within fourteen (14) days of receipt of its response. The CM should follow up to ensure that corrective actions have been implemented.
 - 4. After the CA notifies a laboratory, in writing, that it has been downgraded to "provisionally certified" status for procedural, administrative, equipment, or personnel deficiency, the laboratory should correct its problem within thirty (30) days.
- C. Procedures for Downgrading Certification Based on a PT Study:
 - 1. If a laboratory does not analyze a PT sample/study annually or semiannually as required they must participate in the next available PT study. If the lab does not participate, they will be downgraded to provisionally certified.
 - 2. If a chemical lab fails two consecutive studies for the same analyte and method, they must analyze and pass two consecutive studies for that analyte and method. If they fail these studies, they will be downgraded for those analytes. If the analyte is part of a group, they will be downgraded for the entire group. The same applies to microbiological labs which are certified exclusively by DWLCP after one study.
 - 3. If the lab is downgraded the CA must notify the Laboratory Director, Quality Assurance Officer, or owner by emailing a signed pdf letter of its intent to downgrade within fourteen (14) days from becoming aware of the situation warranting downgrading. A hard copy of the letter is also mailed to the laboratory's business address of record.

XI. Certification Denial and Revocation:

- A. Criteria for Denial of an initial application: Denial shall mean to refuse to accredit a laboratory applying for initial certification or resubmission of initial application.
 - 1. Failure to submit an accurate application.
 - 2. Failure of laboratory staff to meet the personnel qualifications (education, training, and experience requirements) as required.
 - 3. Failure to successfully analyze and report PT studies annually (or as required by accrediting authority).
 - 4. Failure to demonstrate the ability to upload data to SDWIS or current database of record.

- 5. Failure to respond to an onsite audit report with a corrective action report within the required thirty (30) calendar days after receipt of the audit report (Microbiological labs).
- 6. Failure to pass required onsite audit(s).
- 7. Denial of entry during normal business hours for an onsite audit as required.
- 8. The lab does not have the intention or ability to analyze compliance samples for public water systems in NM.
- 9. The DWLCP already has enough certified laboratories to meet the SDWA compliance analysis demand for any analyte.

If the laboratory is not successful in addressing the deficiencies as required by the standards and has been denied certification, the laboratory must wait **six months** before reapplying for certification.

- B. Criteria for Revoking Certification: A laboratory shall be downgraded from certified, provisionally certified, or interim certified status to "not certified" for a particular analyte or group of analytes for the following reasons:
 - 1. Reporting PT data from another laboratory as its own.
 - 2. Falsification of data or other deceptive practices.
 - 3. Failure to use the analytical methodology specified in the regulations.
 - 4. Failure by a provisionally certified laboratory to successfully analyze a PT study for a particular analyte within the acceptance limits specified.
 - 5. Failure by a provisionally certified laboratory to correct/address deviations/findings identified during the onsite evaluations.
 - Persistent failure by a provisionally certified laboratory to report or notify the client/submitter according to the requirements specified in Section IX Maintaining Certification.
 - 7. Refusal to participate in an onsite evaluation.
- C. Procedure for Denying/Revoking certification:
 - 1. The CA should notify the laboratory, in writing by email with a signed pdf letter of the intent to revoke (or deny) certification.
 - 2. If the laboratory wishes to challenge this decision, a notice of appeal should be submitted in writing to the CA within fourteen (14) days of receipt of the notice of intent to revoke (or deny) certification. If no notice of appeal is filed, certification shall be revoked (or denied).
 - The notice of appeal should be supported with an explanation of the reasons for the challenge and must be signed by a responsible official from the laboratory such as the president/owner for a commercial laboratory, or the laboratory supervisor in the case of a municipal laboratory.
 - 3. Within fourteen (14) days of receipt of the appeal, the CA will decide and notify the laboratory by email.

If the appeal is denied the CA shall immediately revoke (or deny) the laboratory's certification. Once the certification is revoked (or denied), a laboratory may not analyze drinking water samples for compliance until its certification has been reinstated.

If the appeal is accepted the CA should take the appropriate measures to re- evaluate the facility and notify the laboratory, in writing by email of its decision within fourteen (14) days of the reevaluation.

XII. Upgrading or Reinstatement of Certification:

Through a written request, a laboratory may seek upgrading or reinstatement of certification, when, and if, the laboratory can demonstrate to the CA's satisfaction that the findings which produced provisionally certified status or revocation, have been corrected. This may include an onsite evaluation, successful PT study or any other measure the CA deems appropriate.

XIII. Certification Evaluation:

Laboratories performing analysis of drinking water under the SDWA are required to operate a formal Quality Control/Management program as outlined in the labs QAP.

Certification approval is dependent on an evaluation of information gathered through the application packet, the onsite audit, and reported PT studies. The evaluation is based on the elements described specifically in Chapter IV: Critical Elements of Chemistry and Chapter V: Critical Elements for Microbiology in the EPA Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5th Ed. (81 5-R-05-004, January 2005). The SLD Microbiology Onsite Audit Manual will also provide detailed expectations of the onsite audit portion of the certification review for microbiological labs in New Mexico.

The following sections describe the criteria used to evaluate a drinking water laboratory certification application.

A. Personnel: All personnel shall be responsible for complying with all QA/ QC requirements that pertain to their organizational/technical function. Laboratory Manager, supervisors, staff, and QA Officer must meet the necessary education, training, technical knowledge, and experience for their assigned functions. Personnel records that include academic background, specialized training courses completed, and types of analyses conducted must be maintained for all laboratory personnel.

The following table summarizes the required education and experience requirements for Chemistry laboratory personnel:

CHEMICAL LABORATORY PERSONNEL REQUIREMENTS			
Personnel	Education	Experience	Responsibilities
Laboratory Supervisor	Bachelor's degree in Chemistry or equivalent	Minimum one year analyzing drinking water samples; working	Ensure all laboratory personnel have demonstrated ability to satisfactorily perform the

		knowledge of quality assurance principles	analyses to which they are assigned and that all data meet QA and regulatory requirements
Laboratory Analyst	Bachelor's degree in Chemistry or equivalent	Minimum one year analyzing drinking water samples; specialized training for analytical equipment or apprenticeship with experienced analyst (data must be reviewed and validated by qualified analyst or supervisor until training requirements are met)	Adhere to required QC procedures according to the Laboratory's QA Plan
Technician	High school diploma or equivalent	Completion of method training program under experienced analysts and six months of analyzing drinking water samples	Adhere to required QC procedures according to the Laboratory's QA Plan

NOTE: The CA may waive the need for the above specified academic training, on a case-by-case basis, for highly experienced analysts. The CA may also waive the need for the above specified training, on a case-by case basis, for supervisors of laboratories associated with drinking water systems that only analyze samples from that system. If such a waiver for supervisor training is granted, the CA will prepare a written and signed justification for such a waiver and have it available for inspection. Laboratories must also keep a copy of the waiver.

The following table summarizes the required education and experience requirements for microbiological laboratory personnel:

MICROBIOLOGICAL LABORATORY PERSONNEL REQUIREMENTS			
Personnel	Education	Experience	Responsibilities
Laboratory	Bachelor's degree in	Minimum two weeks	Ensure all laboratory
Supervisor/	microbiology, biology, or	training at federal or state	personnel have
Consultant	equivalent; if not	agency or academic	demonstrated ability to
(Consultant	microbiology, then at least	institution in	satisfactorily perform the
must be	one college-level	microbiological analysis of	analyses to which they are
	microbiology laboratory	drinking water or 80 hours	assigned and that all data

accepted by	course that covered	of on-the-job training in	meet QA and regulatory
CA)	environmental	water microbiology at a	requirements
	microbiology;	certified laboratory or	
		other training acceptable	
		to the CA	
Laboratory	High school diploma or	Minimum three months	Demonstrate acceptable
Analyst	equivalent	bench experience in	results on unknown
		water, milk, or food	samples
		microbiology and training	
		acceptable to CA in	
		microbiological analysis of	
		drinking water and	
		minimum 30 days on-the-	
		job training in drinking	
		water microbiology under	
		an experienced analyst	

NOTE: For New Mexico microbiological laboratories the SLD CO will evaluate the academic training and experience of the laboratory staff during the onsite audit. If a waiver is deemed appropriate the audit report serves as the written waiver.

- B. Laboratory Facilities: Facilities must meet all requirements so that the integrity and security of samples collected is maintained. Facilities should be clean, climate controlled, well-lit, and adhere to all applicable Occupational Safety and Health Administration (OSHA) standards.
- C. Laboratory Equipment, Instrumentation and Supplies: The laboratory must have all equipment, instrumentation and supplies needed to perform the approved methods for which certification has been requested. All equipment must be maintained and calibrated as required. Equipment must also have the necessary accuracy to meet method requirements. Chemicals and reagents must meet all requirements for source, purity, use, storage, and disposal. Glassware must be cleaned and stored properly.
- D. Laboratory Safety: Safety criteria are not covered by the DWLCP. However, all laboratories should follow a documented Chemical Hygiene Plan in their common practices, and ensure personnel are trained on these practices. Each laboratory should follow personal protection guidelines as appropriate. Safety Data Sheets should be available for all hazardous materials maintained on laboratory premises. Labs should follow all appropriate OSHA standards. This does not need to be provided to the DWLCP.
- E. Chain-of-Custody: Laboratories should ensure all samples have sufficient information to process the sample and upload the results into SDWIS or the current database of record before analysis. This is done using a COC form and written COC procedure that allows for the legal documentation and defensibility of a samples. The COC procedure can include electronic methods for logging and tracking samples. This is typically done using barcode labels and

tracking software. The COC form must meet all reporting information requirements and be approved or issued by the CA. The following information must be included on the COC form (items in red are only for microbiological samples):

- 1. Name, address, phone number, email for lab for the lab
- 2. Lab ID number
- 3. Water Supply System name and number
- 4. If the sample is chlorinated and what is the free/total chlorine residual.
- 5. Type of sample i.e. routine, repeat, triggered, or special. Is it a compliance sample (yes or no)?
- 6. The sample point ID number. RT###, RP####, or SP#######1 for routine, repeat, or groundwater samples respectively. For repeat samples also include the original sample ID number. For triggered ground water samples, repeat ground water samples, E. *coli* enumeration, and special samples include the Facility ID#.
- 7. For E. coli. Enumeration samples include the turbidity in NTU.
- 8. Sample location.
- 9. Sample pH, temperature in Celsius, and conductivity in μ S/cm.
- 10. Analytical Method(s)
- 11. Sample/Cooler temp at the lab, and if the cooler has ice.
- 12. Does the sample have a custody seal and is it intact.
- 13. Type of preservative if any.
- 14. Sampler name, Utility Operator Certification Program ID number (mandatory for compliance samples), signature, and contact information.
- 15. Date and time of sample collection.
- 16. Name, signature, time, and date for the people that relinquish and receive the sample at the lab.
- 17. Any important comments about field or sample conditions.
- 18. Test start and end date and time. Volume tested in mL, Total Coliform and E. *coli*. presence/absence results, E. Coli results, analyst name with date and time, reviewers name with date and time. (Only needed if sample report is part of COC).

Example COCs for microbiological and chemical labs are provided in Appendix H. The laboratory must attempt to obtain complete sample information from the sample collector to process and upload the sample. If the laboratory is unable to contact the sample collector, the sample will be rejected. The submitting sample collector must be notified of the rejected sample within 24 hours of rejection.

F. Sample Collection, Preservation and Handling: Sample collection, preservation, and hold time requirements must be made available to sample collectors for all certified methods analyzed by the laboratory and must meet method and regulatory requirements. The laboratory must have a documented sample rejection procedure and adhere to sample collection and transport requirements. Sample request form documentation must meet requirements to preserve the legal defensibility of all compliance data reported and must be approved by the CA. All accepted samples must have a complete COC and be delivered in a sealed cooler(s) or individual sample container(s); however, samples can be accepted without custody seals, if this is noted on the COC.

Sample temperatures should be noted upon receipt. Samples that arrive at the laboratory within 2 hours of sample collection may not yet have reached the appropriate temperature by

the time they arrive at the laboratory due to the proximity of a public water system to the laboratory. These samples should be considered acceptable **ONLY** if packed on ice or with frozen gel/ice packs immediately after sample collection and hence, delivered while the samples were in the process of reaching an appropriate equilibrium temperature.

NOTE FOR MICROBIOLOGICAL SAMPLES: The time from sample collection to placement of the sample in the incubator (i.e. the 'holding time') for total coliforms and fecal coliforms in surface water sources, and heterotrophic bacteria in drinking water, must not exceed eight hours for samples being analyzed in compliance with the Surface Water Treatment Rule (40 CFR § 141.74(a)(1)). Per 40 CFR § 141.704, for surface water E. coli samples being analyzed in compliance with the Long Term 2 (LT2) rule, the holding time for the sample must not exceed 30 hours, unless an exception is granted by the State. The State may approve, on a case-by-case basis, the holding of an LT2 E. coli sample for up to 48 hours if the State determines that analyzing the sample within 30 hours is not feasible.

G. Quality Assurance/Control: It is the responsibility of the laboratory's QA Officer to maintain the plan and ensure laboratory personnel are provided a current version. QA Manuals/Plans describing all QC procedures must be submitted with the certification application. Any specific QC information such as MDL studies, initial demonstration of capabilities, QC sample results, traceability of calibration, reference standards, calibration, support equipment, instrument calibration, and related general requirements shall be assessed during the onsite audit.

XIV. Requirements for QAP:

The laboratory QAP should be a separately prepared text. However, documentation for many of the listed QAP items may be made by reference to appropriate sections of this manual, the laboratory's standard operating procedures (SOPs), or other literature (e.g., promulgated methods, Standard Methods for the Examination of Water and Wastewater, etc.) The QAP must be reviewed annually and revised as necessary.

The QAP must meet the QC criteria given in the EPA Manual for the Certification of laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, 5th Ed. (815-R-05-004, January 2005) and the EPA Requirements for Quality Management Plans (EPA QA/R-2), as applicable to the laboratory.

For NM microbiological labs the DWLCP has created a QAP template. To request this template, send an email to MMENV-DWBlabcert@state.nm.us. If a section of the template is not applicable to the laboratory it may be removed, or a brief explanation may be provided to explain why it is not applicable.

- A. Required Elements: The following items should be addressed in each QAP. A laboratory QAP should be responsive to the following items while remaining brief and easy to follow. Minimizing paperwork, while improving dependability and quality of data, are the intended goals.
 - 1. The first page should be the title page, which should include:
 - i. The name of the document
 - ii. The document control number for review/revision tracking purposes
 - iii. The latest revision number and effective date

iv. Approval signatures from the lab director/manger, lab supervisor(s), and the QA officer. These signatures may be electronic. The signature page maybe a separate page from the title page.

- 2. Management and Organization:
 - i. A statement of the overall goals of the QA system for the lab.
 - ii. An organizational chart including QA personnel
 - iii. Job descriptions for QA staff and management with a focus on how they work together to implement the labs QA Plan.
 - iv. A brief description of the lab activities that are controlled by the QA Plan.
 - v. A brief description of how management ensure that employees read and follow the QA Plan.
- 3. Quality System Components: A brief description of the main components of the QA Plan and who is responsible for each component. Components include but are not limited to:
 - i. What QA documentation such as audit reports, corrective action reports, data assessments, etc. do the lab use.
 - ii. How the lab performs internal assessments of management, projects, data, SOPs, the QA program including the QA Plan, etc. These internal assessments should be performed at least once a year.
 - iii. How the lab makes sure auditors have no conflict of interest and to the extent possible are not involved in the work they are auditing.
 - iv. How the lab makes sure auditor have access to documents, other staff, records etc.
 - v. How the lab identifies and corrects problems, and how they track this process.
 - vi. What do labs do in the case of failed PT studies.
 - vii. What external audits the lab has done
 - viii. What PT programs the lab uses
 - ix. How the lab identifies clients' Data Quality Objectives
- 4. Personnel Qualifications and Training: Describe the following components of the training program:
 - i. Who is responsible for determining what training, education, and skills each position requires.
 - ii. Who conducts the training
 - iii. How the training is conducted
 - iv. How the training is documented and tracked.
- 5. Items and Services: A brief description of the plan for the use of outside goods and services and who is responsible for each component. Components include but are not limited to:
 - i. How the lab documents any contracts, grants, service agreements, etc.
 - ii. How the lab chooses and approves suppliers and subcontractors.
 - iii. How the lab ensures that good and services meet quality requirements.
 - iv. How the documents and tracks certificates of quality for outside goods such as standards, sterile sample containers, etc.
- 6. Laboratory sample receipt and handling procedures: should include the following information:
 - i. If the lab uses bound laboratory notebooks (should be filled out in ink; entries dated and signed) or a secure, password protected, electronic data base

- ii. How the lab stores unprocessed and processed samples at the proper temperature and how the lab isolates samples from laboratory contaminants and standards
- iii. How the lab ensures that holding times are not exceeded
- iv. How the lab tracks samples from receipt by the laboratory through analysis to disposal. This process includes COC forms, which maybe electronic
- v. Specify criteria for rejection of samples which do not meet shipping, holding time and/or preservation
- vi. Requirements and procedures for notification of sample originators.
- 7. Analytical Procedures Including Instrument Calibration: should include the following information (may reference SOPs):
 - i. Type of calibration used for each method and frequency of use;
 - ii. Calibration standards' source, age, storage, labeling;
 - iii. How the lab performs data comparability checks (can be a test with a confirmation column or round robin test)
 - iv. How the lab uses control charts
 - v. Cite the complete method manual
 - vi. Description of quality control procedures required by the methods that need to be followed. Include types of quality control (QC) checks and the frequency of their use:
 - For chemistry and radiochemistry test should include or reference:
 - o instrument performance check standards;
 - o frequency and acceptability of method detection limit (MDL) calculations;
 - o frequency and acceptability of demonstration of low-level capability;
 - o calibration, internal and surrogate standards;
 - laboratory reagent blank, field reagent blank and trip blank;
 - field and laboratory matrix replicates;
 - o quality control and proficiency testing samples;
 - laboratory fortified blank and laboratory fortified sample matrix replicates;
 - o initial demonstration of method capability;
 - use of control charts;
 - qualitative identification/confirmation of contaminants.
 - For microbiology test should include or reference:
 - positive and negative culture controls;
 - o confirmation/verification of presumptive total coliform positive samples;
 - sterility controls
 - proficiency testing and quality control samples.
- 8. Data reduction, validation, reporting, and verification: should include the follow information (may reference SOP):
 - i. Description of the data reduction process i.e., method of conversion of raw data to mg/L, picocuries/L, coliforms/100 mL, etc.
 - ii. Description of the data validation process
 - iii. Description of reporting procedures, include procedures and format
 - iv. Description of the data verification process

- v. Description of reporting of counting uncertainties and confidence levels (for radiochemistry only)
- vi. Description of procedure for data corrections for hard copy and digital data.
- 9. Documents and Records: A brief description of the plan for documents and records and who is responsible for each component. Components include but are not limited to:
 - i. How and when does the lab write/review SOPs and the QA Plan. SOPs need to accurately reflect all phases of current laboratory activities
 - ii. How are documents approved. Electronic signatures are acceptable on pdf documents.
 - iii. How do staff identify and access the latest version of documents. How are old versions of documents archived?
 - iv. How are documents and their revision/revision tracked. This can be done in a spreadsheet. Labs should also provide a list of SOPs.
 - v. How are records/documents stored. The QA Officer needs to have the most recent version of QA documents on file. The lab must follow federal guidelines for record retention time. Electronic records must also have a backup, so they can be recreated. Electronic records must be properly secured.
- 10. Computer Hardware and Software: This includes automated data acquisition systems, data analysis software, etc.
 - i. Development, installation, and testing of new hardware and software when created by the lab.
 - ii. How the lab documents and test any changes to hardware and software.
 - iii. How the lab evaluates off the shelf hardware and software.
 - iv. How the lab checks that data produced by automated systems meets QA/QC requirements.
- 11. Quality Improvement: How does the lab find areas for improvement and how does the lab carry out these improvements. Suggestions can come from internal and external sources.

XV. Laboratory Ethics and Fraud Detection/Deterrence:

Laboratories are encouraged to have an ethics policy and implement a fraud detection and deterrence policy/program, including use of the following, as appropriate:

- 1. Use data validation and verification techniques; and
- 2. Use analyst notation and sign-off on manual integration changes to data.
- A. Four key areas of concern include:
 - 1. Inappropriate procedure: A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.
 - Laboratory fraud: The deliberate falsification during reporting of analytical and quality
 assurance results that failed method and contractual requirements to make them appear
 to have passed requirements.

3. Data quality: The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.

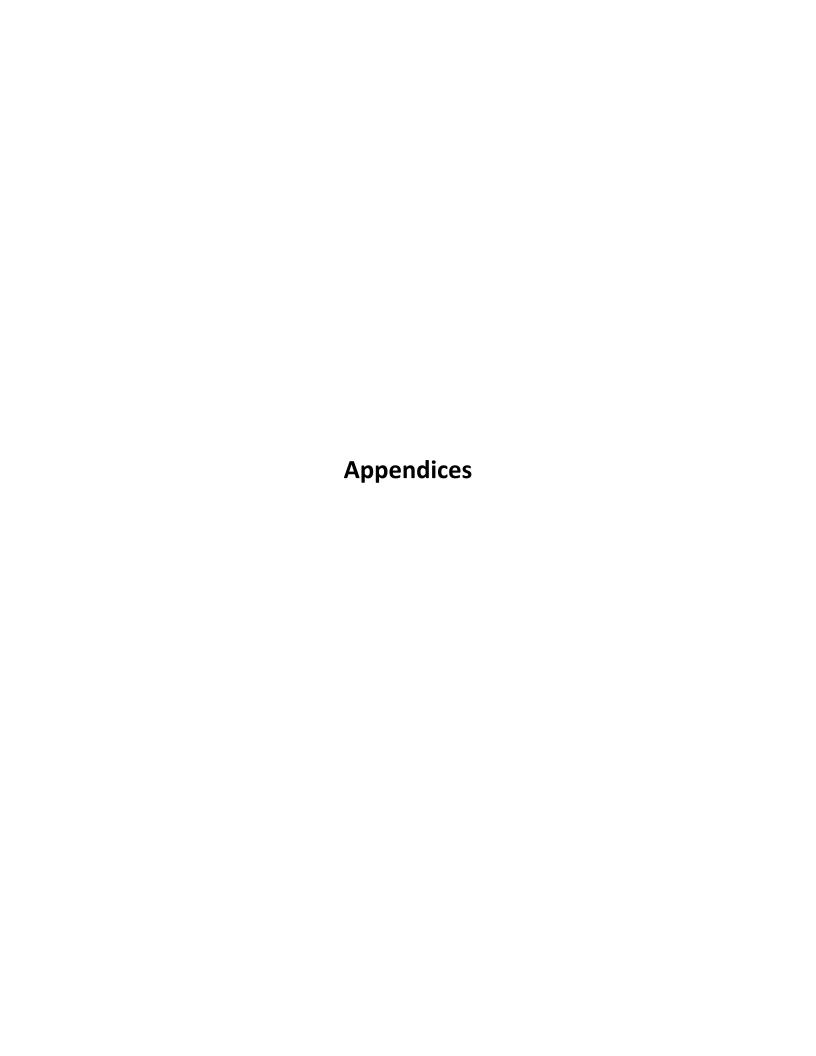
4. Laboratory integrity: The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

NOTE: It is unlawful to knowingly provide false information related to a public water systems and material to the protection of public health. Doing so could result in misdemeanor charges.

B. If a laboratory employee suspects that fraudulent behavior is occurring, they should report it to the DWLCP CA. COs should familiarize themselves with their State and/or Regional reporting procedures and follow them upon becoming aware of suspected fraudulent behavior. EPA's Office of Enforcement and Compliance Assurance may also be used as a resource (www.epa.gov/compliance/complaints/index.html) for questions and concerns related to suspected fraud.

Laboratories are particularly encouraged to become familiar with the following prohibited practices:

- 1. Fabrication, falsification, or misrepresentation of data;
- 2. Improper clock setting (time traveling) or improper date/time recording;
- 3. Unwarranted manipulation of samples, software, or analytical conditions;
- 4. Misrepresenting or misreporting QC samples;
- 5. Improper calibrations;
- 6. Concealing a known analytical or sample problem;
- 7. Concealing a known improper or unethical behavior or action; and
- 8. Failing to report the occurrence of a prohibited practice or known improper or unethical act.



APPENDIX A



Drinking Water Laboratory Certification Program Application

This application packet must be filled out completely to be considered for drinking water laboratory certification in New Mexico (NM). When completing the application do <u>NOT</u> change the format of the application, or insert any other documents, or it will be rejected.

Renewal applications must be submitted <u>at least</u> 90 days prior to certification expiration. <u>NOTE</u>: We will no longer be sending out reminders to submit your laboratory's renewal application.

All information requested within this application must be submitted <u>each time</u> a new application is submitted. Do not put "previously submitted" or "on file." If information required is enclosed within another document submitted, please state where it may be found.

Failure to meet the requirements to maintain certification may constitute grounds for downgrading or revoking certification. To re-establish certification, a new application packet should be filled out and submitted, along with all appropriate supporting documentation.

The Drinking Water Laboratory Certification Program (DWLCP) accepts national drinking water certification from A2LA, EPA, and TNI to process New Mexico reciprocity certifications. Reciprocity certifications are only established for the duration of the American Association for Laboratory Accreditation (A2LA), Environmental Protection Agency (EPA) or The NELAC Institute (TNI) accreditation.

If the DWLCP is your primary accrediting body for microbiological analyses, you must schedule your on-site audit with Erica Swanson at SLD when submitting your application; (505) 383-9120 Erica.Swanson@state.nm.us This should be scheduled well in advance for the on-site audit to occur before your certification expires. After you have requested an on-site audit from SLD you must notify the DWB Quality Assurance Coordinator and let them know the date it is scheduled for. Microbiological laboratory certifications may be good for up to three (3) years if successful PT studies results are reported annually and all other requirements for maintaining certification are met.

Electronic submission of applications is required. Completed electronic applications and any questions must be submitted to: NMENV-DWBlabcert@state.nm.us

The following are requirements by Drinking Water Laboratory Certification Program (DWLCP) to receive certification:

- 1. The DWLCP only certifies laboratories for analytes and methods that are identified as acceptable for meeting compliance under Safe Drinking Water Act (SDWA), state regulations NMAC 20.7.10 and federal regulations 40 CFR 141-143.
- Laboratories must agree to accepting a Drinking Water Bureau (DWB) issued Chain of Custody (COC) or
 ensure their COC is approved by the DWLCP and contains the necessary information required by SDWA
 regulations to successfully upload information into the DWB database of record at the time of upload.
- 3. Laboratories must maintain capabilities or credentials necessary to provide data uploads as required by DWB. Failure to maintain upload capabilities may be grounds for downgrading or revoking certification.

PART ONE: Laboratory Identification Date application submitted: Type of Application: □ Renewal □Amendment □New ☐ Reciprocity Legal Name of Laboratory: Laboratory ID#: Phone: Email: _____ Mailing address: Physical address (if different than mailing address): Billing address (if different than mailing address): Owner of laboratory: _____ Phone: _____ Laboratory Type (choose all that apply): □Public Water System □Public Wastewater System □Commercial □Other: ______ Primary Accrediting Authority: _____ Expiration Date: Date of last onsite audit: Secondary Accrediting Authority: ______ Expiration Date: _____ Date of last onsite audit:

Note: Access to all information collected or generated by the DWLCP is regulated by the Inspection of Public Records Act (NMSA 1978 Section 14-2-1 et seq. NMED Policy 05-02). Except under special circumstances, records must be made available to the public upon written request. No notification to the applicant laboratory will be made if records relating to it are requested.

PART TWO: Personnel Qualifications

Key personnel (Laboratory Director, QA Officer, and all Laboratory Supervisors) must submit a copy of their resumes with the enclosed signed certification statement. Attach additional information pertinent to your education, training, employment, etc.

Revised: September 21, 2021

Laboratory and Laboratory Supervisor Certification

I/We the undersigned certify that personnel listed in the technical personnel list have the appropriate educational and/or technical background to perform all tests for which the laboratory is seeking accreditation. (EPA 815-R-05-004; January 2005)

Laboratory Director (print name)	Phone Number
Signature and Date	Email
QA Officer/Manager (print name)	Phone Number
Signature and Date	Email
Laboratory Supervisor (Organics) (print name)	Phone Number
Signature and Date	Email
Laboratory Supervisor (Inorganics) (print name)	Phone Number
Signature and Date	Email
Laboratory Supervisor (Microbiological) (print name)	Phone Number
Signature and Date	Email
Laboratory Supervisor (Radiological) (print name)	Phone Number
Signature and Date	Email
Laboratory Supervisor (Asbestos) (print name)	Phone Number
Signature and Date	Fmail

Revised: September 21, 2021

All technical personnel must be listed below. Attach additional pages if more room is necessary.

Technical Personnel List

Name	Positions/Titles	Methods Performed

PART THREE: Test Method-Analyte Selection

The DWLCP is designed to fulfill the compliance needs of the NMED Drinking Water Bureau (DWB) and requires all NM certified laboratories to adhere to EPA approved drinking water methods.

The DWLCP requires that laboratories seeking certification for groups of analytes as outlined under the SDWA (see 40 CFR §141-National Primary Drinking Water Regulations, Subpart C-Monitoring and Analytical Requirements & 40 CFR §143-National Secondary Drinking Water Regulations), must be certified for all the parameters of a specific group covered under the rule; *no partial certifications will be issued* (See table below). Conversely, if a laboratory loses certification for a particular analyte, the whole group is removed from certification. For example, the lab must certify for all SOCs not just ones by a specific method. Water Systems are required to test for all analytes in a group at the same time, so labs must be certified for the entire

group. For reciprocity certifications methods and analytes must match scope of the primary certificate. All combinations of methods and analytes must have a passing PT test each. All methods must have a written SOP.

Indicate method(s) for which the laboratory is seeking certification. For methods with more than one version please specify the version. The method/version must match the method/version used for PT study results.

SDWIS CODE - Drinking Water Analytes	METHOD(S) TO BE NM CERTIFIED	
	GANICS	
	s Group (HM)	
1074 - ANTIMONY		
1005 - ARSENIC		
1010 - BARIUM		
1075 - BERYLLIUM		
1015 - CADMIUM		
1020 - CHROMIUM		
1035 - MERCURY		
1036 - NICKEL		
1045 - SELENIUM		
1052 - SODIUM		
1085 - THALLIUM		
Lead and Coppe	er Group (Pb/Cu)	
1030 - LEAD		
1022 - COPPER		
Secondary Pa	rameters (SEC)	
1002 - ALUMINUM		
1017 - CHLORIDE		
1905 - COLOR		
2905 - FOAMING AGENTS		
1028 - IRON		
1032 - MANGANESE		
1920 - ODOR		
1050 - SILVER		
1055 - SULFATE		
1930 - TOTAL DISSOLVED SOLIDS (TDS)		
1095 - ZINC		
Individual Analytes/Parameters		
1094 - ASBESTOS		
1004 - BROMIDE		
1024 - CYANIDE		
1025 - FLUORIDE		
1915 - HARDNESS, TOTAL		

1031 - MAGNESIUM	
1040 - NITRATE	
1041 - NITRITE	
1038 - NITRATE + NITRITE	
1042 - POTASSIUM	
OI	RGANICS
Volatile Organic Compounds Group (VOC)	
2981 - 1,1,1-TRICHLOROETHANE	
2985 - 1,1,2-TRICHLOROETHANE	
2977 - 1,1-DICHLOROETHYLENE	
2378 - 1,2,4-TRICHLOROBENZENE	
2968 - 1,2-DICHLOROBENZENE	
2969 - 1,4-DICHLOROBENZENE	
2980 - 1,2-DICHLOROETHANE	
2380 - CIS-1,2-DICHLOROETHENE	
2979 - TRANS-1,2-DICHLOROETHENE	
2983 - 1,2-DICHLOROPROPANE	
2990 – BENZENE	
2982 - CARBON TETRACHLORIDE	
2989 – CHLOROBENZENE	
2964 - DICHLOROMETHANE (DCM or	
METHYLENE CHLORIDE)	
2992 - ETHYLBENZENE	
2996 – STYRENE	
2987 - TETRACHLOROETHYLENE (PCE)	
2991 - TOLUENE	
2984 - TRICHLOROETHYLENE (TCE)	
2976 - VINYL CHLORIDE	
2955 - XYLENES, TOTAL	
Synthetic Organic C	ompounds Group (RSOC)
2110 - 2,4,5-TP (SILVEX)	
2105 - 2,4-D	
2050 - ATRAZINE	
2306 - BENZO(A)PYRENE	
2010 - LINDANE (BHC-GAMMA)	
2046 - CARBOFURAN	
2959 - CHLORDANE	
2031 - DALAPON	
2035 - DI(2-ETHYLHEXYL) ADIPATE	
2039 - DI(2-ETHYLHEXYL) PHTHALATE	
2931 - DIBROMOCHLOROPROPANE	
2041 - DINOSEB	

2032 - DIQUAT	
2033 - ENDOTHALL	
2005 - ENDRIN	
2946 - ETHYLENE DIBROMIDE (EDB or 1,2-	
DIBROMOETHANE)	
2034 - GLYPHOSATE	
2065 - HEPTACHLOR	
2067 - HEPTACHLOR EPOXIDE	
2274 - HEXACHLOROBENZENE	
2042 - HEXACHLOROYCLOPENTADIENE	
2051 - LASSO (ALACHLOR)	
2015 - METHOXYCHLOR	
2036 - OXAMYL (VYDATE)	
2326 - PENTACHLOROPHENOL	
2040 - PICLORAM	
2037 - SIMAZINE	
2383 - PCBs (as AROCLORS)	
2020 - TOXAPHENE	
Disinfectant Byproducts Group (DBP2)	
Total Trihalomethanes (TTHM)	
2943 - BROMODICHLOROMETHANE	
2942 - BROMOFORM	
2941 - CHLOROFORM	
2944 - DIBROMOCHLOROMETHANE	
2950 - TOTAL TRIHALOMETHANES	
Total Haloacetic Acids (HAA5)	
2453 - MONOBROMOACETIC ACID	
2454 - DIBROMOACETIC ACID	
2451 - DICHLOROACETIC ACID	
2452 - TRICHLOROACETIC ACID 2450 - MONOCHLOROACETIC ACID	
2456 - TOTAL HAA5	
	Substances (PFAS) Groups
11-CHLOROEICOSAFLUORO-3-OXAUNDECANE-1-	substances (FIA5) Gloups
SULFONIC ACID (11CI-PF3OUdS) **	
9-CHLOROHEXADECAFLUORO-3-OXANONANE-1-	
SULFONIC ACID (9CI-PF3ONS) **	
4,8-DIOXA-3H-PERFLUORONONANOIC ACID (ADONA) **	
HEXAFLUOROPROPYLENE OXIDE DIMER ACID	
(HFPO-DA) **	
PERFLUOROBUTANESULFONIC ACID (PFBS) **	
PERFLUORODECANOIC ACID (PFDA) **	

PERFLUORODODECANOIC ACID (PFDoA) **	
PERFLUOROHEPTANOIC ACID (PFHpA) **	
PERFLUOROHEXANOIC ACID (PFHxA) **	
PERFLUOROHEXANESULFONIC ACID (PFHxS) **	
PERFLUORONONANOIC ACID (PFNA) **	
PERFLUOROOCTANOIC ACID (PFOA) **	
PERFLUOROOCTANESULFONIC ACID (PFOS) **	
PERFLUOROUNDECANOIC ACID (PFUnA or PFUnDA) **	
1H,1H, 2H, 2H-PERFLUOROHEXANE SULFONIC ACID (4:2FTS) *	
1H,1H, 2H, 2H-PERFLUOROOCTANE SULFONIC ACID (6:2FTS) *	
1H,1H, 2H, 2H-PERFLUORODECANE SULFONIC ACID (8:2FTS) *	
NONAFLUORO-3,6-DIOXAHEPTANOIC ACID (NFDHA) *	
PERFLUOROBUTANOIC ACID (PFBA) *	
PERFLUORO(2-ETHOXYETHANE) SULFONIC ACID (PFEESA) *	
PERFLUOROHEPTANESULFONIC ACID (PFHpS) *	
PERFLUORO-4-METHOXYBUTANOIC ACID (PFMBA) *	
PERFLUORO-3-METHOXYPROPANOIC ACID (PFMPA) *	
PERFLUOROPENTANOIC ACID (PFPeA) *	
PERFLUOROPENTANESULFONIC ACID (PFPeS) *	
N-ETHYL PERFLUOROOCTANESULFONAMIDOACETIC ACID (NEtFOSAA) *	
N-METHYL PERFLUOROOCTANESULFONAMIDOACETIC ACID (NMeFOSAA) *	
PERFLUOROTETRADECANOIC ACID (PFTA or PFTeA) *	
PERFLUOROTRIDECANOIC ACID (PFTrDA) *	
*Group for Method 533, *Group for Method 537.	1 Lab can request both methods. Must request
entire group for chosen method(s).	
Individual	Parameters
1011 - BROMATE	
1008 - CHLORINE DIOXIDE	
1006 - CHLORAMINE	
2063 - 2,3,7,8 -TCDD (DIOXIN)	
2919 - DISSOLVED ORGANIC CARBON (DOC)	
2920 - TOTAL ORGANIC CARBON (TOC)	
2923 - SPECIFIC UV ABS (SUVA)	

RADIOLOGICAL				
Radiological Group (NRAD)				
4002 - GROSS ALPHA, INCL. RADON & U				
4100 - GROSS BETA PARTICLE ACTIVITY				
4020 - RADIUM-226				
4030 - RADIUM-228				
4006 - COMBINED URANIUM (U-MASS)				
Individual Radiol	ogical Parameters			
4172 - STRONTIUM-89				
4174 - STRONTIUM-90				
4102 - TRITIUM				
MICROBI	MICROBIOLOGICAL			
3100 - TOTAL COLIFORM				
3014 - E. COLI				
3015 - CRYPTOSPORIDIUM				
3008 - GIARDIA				
TC/EC ENUMERATION				

PART FOUR: Quality Assurance Documentation

A laboratory must submit copies of the following items for review:

- 1. Current copy of laboratory Quality Assurance Manual/Quality Assurance Plan (QAM/QAP).
- 2. Current copies of laboratory quality systems documentation including any administrative standard operating procedures (SOPs) referenced in the QAM/QAP.
- 3. Current copies of analytical SOPs for each requested method.
- 4. Current copies of Chain of Custody SOP, Sample Receipt SOP, and Subcontractor SOP.
- 5. Reciprocity certifications must also submit a copy of their EPA/TNI/A2LA certificate, scope of accreditation, last on-site audit, corrective action response, and audit closure letter.
- 6. Last two sets of PT study results for each analyte and method for which certification is being requested. Laboratories currently certified by DWLCP and requesting an amendment to their scope of accreditation must submit 2 successful sets of PT sample results for the new analytes and methods to be added to their scope.

<u>NOTE</u>: All chemical and microbiological laboratories must submit their QAM/QAP, SOPs, and PT results to the DWLCP annually at NMENV-DWBlabcert@state.nm.us. The PT study results must be submitted even if your PT provider is already sending results directly to the DWLCP as they become available.

Chemical laboratories may submit these documents along with their annual certification renewal application. They are also required to submit their annual Method Detection Limit (MDL) studies and the associated Minimum Reporting Levels (MRL) for each method and analyte for which they are seeking certification.

PART FIVE: Instrumentation Listing

Please complete the following chart for each piece of equipment used in your laboratory in the performance of the requested methods. A reference to your QAM may be substituted.

Type of Instrument, i.e. ICP, ICP-MS	Instrument ID#	Manufacturer	Model#	Methods Performed

PART SIX: Proficiency Testing Verification

Certified laboratories must successfully analyze proficiency testing (PT) studies at least annually for each analyte and method for which they are requesting continued certification. While PT studies from any accredited provider are permitted, DWLCP recommends PT providers accredited by The NELAC Institute (TNI). It is the laboratory's

responsibility to notify their PT provider that PT study results <u>must</u> be provided to DWLCP at <u>NMENV-DWBlabcert@state.nm.us</u>

I understand that continued participation in a PT program is essential to maintain the laboratory's continued certification. I understand that PT samples must be analyzed successfully in a drinking water matrix for each analyte and method for which the laboratory wishes to be certified. The methods listed on the laboratory's certificate must be the methods by which the PT samples were analyzed.

I am also aware that failure to participate in an accredited PT program could mean loss of approval for affected parameters. I further agree that all PT samples are handled (i.e. managed, analyzed, and reported) in the same manner as real drinking water samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis and that no additional quality control measures are utilized along with the PT samples. I further understand that failure to analyze PT samples as real drinking water samples could mean downgrade/loss of certification.

Laboratory Director (print name)	Signature	Date
QA Officer/Manager (print name)	Signature	Date

PART SEVEN: Certification by Applicant and Records Access

The applicant understands and acknowledges that the laboratory is required to be continually in compliance with NMAC 20.7.10.501 and shall be subject to suspension, revocation and denial of certification as specified therein. The applicant acknowledges that the department may make unannounced on-site audits and that a refusal to allow entry by the department's representatives is grounds for denial or revocation of certification. The applicant also understands and acknowledges that the laboratory is subject to the enforcement and penalty provisions of the primary and/or secondary accrediting authority. The applicant hereby certifies that all drinking water analyses performed are done in accordance with 40 CFR 141-143. The applicant will perform all proficiency testing according to the approved method and will report all SDWA compliance data to the NM Safe Drinking Water Information System (SDWIS), or current database of record at time of upload.

We hereby certify that we are authorized to sign this application on behalf of the applicant/owner and that there are no misrepresentations in my answer to the questions on this application.

Laboratory Director (print name)	Signature	Date
QA Officer/Manager (print name)	Signature	Date
Laboratory Supervisor (Org) (print name)	Signature	Date
Laboratory Supervisor (Inorg) (print name)	Signature	 Date

Appendix A

DWLCP Application

Revision#5.0 Revised: September 21, 2021

Page 11 of 12

Laboratory Supervisor (Micro) (print name)	Signature	Date
Laboratory Supervisor (Rad) (print name)	Signature	Date
Laboratory Supervisor (Asbestos) (print name)	Signature	Date
PART EIGHT: Data Reporting Capab	oilities	
It is required that analytical data be uploaded compliance data may be shared quickly and a laboratories certified in NM demonstrate this analyte which certification is requested prior this data upload capability with SDWIS or cur	ccurately, internally, ability by creating ar to certification appro	and externally. The DWLCP requires that all nd uploading a test data set to SDWIS for each oval. Laboratories are required to maintain
Failure to maintain upload capabilities may be	e grounds for downgr	rading or revoking certification.
☐ Laboratory has successfully demonstrated DATE:	I capability to upload	I to SDWIS.
Laboratory needs information on data page	ckaging format to upl	load to SDWIS.

Revision#5.0 Revised: September 21, 2021



Appendix B

DWLCP Checklist for Certification Application

☐ Technical personnel description(s) verified with laboratory supervisor signatures
☐ Resumes for all key personnel (Lab Director, QA Officer, and all Laboratory Supervisors)
☐ Test Method-Analyte Selection table completed
☐ QAP/QAM, with revision #, date, and signature(s) of approval
☐ SOPs for all analytical methods for which you are requesting certification (revision #, date, and signature)
☐ Administrative SOPs referenced in the QAP/QAM, including but not limited to COC SOP, Sample Receiving SOP and Subcontractor SOP, etc.
☐ Copy of the laboratory's COC
☐ Last two sets of PT results (PT results must be submitted even if your PT provider is already sending results directly to the DWLCP as they become available)
☐ Instrument List (may be included in the QAP/QAM)
☐ PT study verification (signed)
☐ Signed certification of information and records access form
☐ Signed Receipt and Acknowledgment of Understanding (Appendix D)
☐ Verification that the SDWIS test upload requirement was met (not applicable for Cryptosporidium/Giardia labs at this time)
☐ Current A2LA/EPA/TNI certificate, scope of accreditation, last on-site audit, corrective action response, and audit closure letter (<i>Reciprocity laboratories only.</i>)
☐ New A2LA/EPA/TNI certificate, scope of accreditation
☐ Annual MDL studies and the associated MRL for each method and analyte for which you are seeking certification <i>(Chemical labs only.)</i>
☐ Date of onsite audit. (If you have requested an onsite audit from SLD (NM microbiological labs only at this time) inform the DWLCP Lab Certification Officer of the date it will be performed.
☐ Audit Report, any corrective action reports from the audit, proof that the audit is closed.

MENT DEPRE

Appendix C

Drinking Water Laboratory Certification Program (DWLCP) Best Practices

- Applications for recertification, along with all supporting documentation must be submitted
 at least 90 days prior to certification expiration. It is a laboratory's responsibility to submit
 the application on time. NOTE: DWLCP will no longer be sending out email reminders.
 Certification renewals also require a full application packet to be submitted. When
 completing the application, do not change the format of the application or it will be rejected.
- 2. If DWLCP is your primary accrediting body for microbiological analyses, you must schedule your onsite audit with Erica Swanson at SLD when submitting your application; (505) 383-9120 Erica.Swanson@state.nm.us Inspections should be scheduled well in advance for the on-site inspection to occur *before* your certification expires.
- 3. DWLCP requires that laboratories seeking certification for groups of analytes as outlined under the SDWA (see 40 CFR §141-National Primary Drinking Water Regulations, Subpart C-Monitoring and Analytical Requirements & 40 CFR §143-National Secondary Drinking Water Regulations), must be certified for all the parameters of a specific group covered under the rule; no partial certifications will be issued (See table in Appendix A). Conversely, if a laboratory loses certification for a particular analyte, the entire group is removed from certification.
- 4. When submitting your application for initial certification or re-certification, you must supply the DWLCP with the following documents:
 - Current Quality Assurance Manual/Quality Assurance Plan (QAM/QAP).
 - Current Standard Operating Procedures (SOPs).
 - Copy of the lab's current Chain of Custody (COC).
 - Last 2 sets of Proficiency Test (PT) study results.
 - Instrument list (may be included in the QAM/QAP).
 - Resumes for all management and supervisory positions.
 - All staff approved to perform analyses must be listed in application.
 - Chemical labs are also required to submit their annual Method Detection Limit
 (MDL) studies and the associated Minimum Reporting Levels (MRL) for each method
 and analyte for which they are seeking certification.

- 5. You must ensure that your PT provider is submitting your PT study results directly to the DWLCP at: NMENV-DWBlabcert@state.nm.us. Please note that this is the only address to have PT study results sent to, do not list individuals as recipients.
- 6. SOPs and the QAM/QAP must be reviewed annually, revised if necessary, and submitted to the DWLCP **annually, per EPA requirements**. Documents must include the new, updated revision number (different revision number for each year), signature of person(s) approving the document for use, and date of approval.
- 7. It is required that laboratories issue a new whole number for each annual review/revision (ex. Rev# 1.0 for 2016, Rev# 2.0 for 2017, etc.). Any other revisions made outside of the annual review should be denoted by decimal numbers (ex. Rev# 2.1, Rev#2.2, etc.).
- 8. Samples submitted for compliance under the SDWA must be submitted with signatures and ID#'s of certified samplers using a COC that meets all the reporting information requirements and is approved by or issued by NMED-DWB; which includes full COC documentation.
- 9. COCs must be complete and accurate.
- 10. All laboratories certified by DWLCP must be able to successfully upload their results into SDWIS. Uploading of data can only be performed by the laboratory personnel listed in the DWLCP application, or as notified by lab for personnel changes.
- 11. Certified laboratories must notify DWLCP, in writing, within 30 days of major changes in personnel, equipment, or laboratory location.
- 12. It is the laboratories' responsibility to notify DWLCP of changes to email, lab addresses, phone numbers, etc., when they change; as well as notifying DWB Finance regarding invoice/billing issues or contract updates/notifications.

This information is further detailed in the NMED-DWB Drinking Water Laboratory Certification Program Guidance Manual. Contact the DWLCP Certification Authority if you have questions or concerns. Bethany Anderson (505) 469-3204 or Bethany. Anderson@state.nm.us



APPENDIX D

Drinking Water Laboratory Certification Program Acknowledgment Form

Receipt and Acknowledgement of Understanding

(Must be signed by Laboratory Director or QA Officer/Manager and returned for certification to be issued.)

I have received a copy of the Drinking Water Laboratory Certification Program Guidance Manual, Revison#4.0. By signing below, I am acknowledging that I am familiar with, and will implement the procedures and requirements as documented in the referenced DWLCP Guidance Manual, as well as all requirements included in the Appendices. I also understand that failure to meet these requirements may lead to a downgrade of certification status or revocation of my certification with the State of New Mexico Drinking Water Bureau.

Laboratory Name:		
Job title:		
Signature	Date	

Please sign and return to:

DWLCP Certification Authority

Drinking Water Bureau

NMENV-DWBlabcert@state.nm.us

Appendix E



Subcontract Laboratory (sub-lab) Request Form

Laboratories seeking to utilize another laboratory (sub-lab) for analyses must complete this form requesting the analytes and methods they are planning to subcontract out.

Person making request (name	and title):			
Requesting laboratory (prima	ry):			
EPA Lab ID#:	<u></u>			
Address:				
City:	State:		Zip:	
Phone number:		Email:		
Contact person(s):				
Sub-lab name:				
EPA Lab ID#:	<u> </u>			
Address:				
City:	State:		Zip:	
Phone number:		Email:		
Contact person(s):				
I understand it is the primary currently certified by the DWI laboratory's responsibility to e The primary laboratory is also Reason for request:	CP for the analyte	es and methods ta from the sub	requested. It is also the lab will be loaded into SI	primary

nalyte Name	Analyte Code	Method	Approved	Initials
CP renresentat	tive (name and title):			
er representat	tive (name and title).			
ature and Date	of Approval:			

Appendix F



Quarterly Quality Assurance Report for Microbiological Laboratories

Name of Laboratory:		
Quarter Year	Lab #	
Month		Totals for Quarter
Number of TC sample results reported		
Number of TC samples rejected		
Number of laboratory errors		
Number of Total Coliform and E coli positive routine samples		
Percent of results reported within 10 days of analysis		
Laboratory official signature:	Da	ate:
Reason for Rejected Samples put a number on the li zero leave blank.	ne to left of tl	he reason. If
frozen sample		
out of temperature		
broken container		
other:		

MEXICO LANGUAGE PROPERTY OF THE PROPERTY OF TH

Appendix F

Quarterly Quality Assurance Report for Chemical Laboratories

Name of Laborato	ory:		
Quarter	Year	Lab #	
	Month		Totals for Quarter
Number of sample results re	ported		
Number of samples rejected			
Number of laboratory errors	5		
Percent of results reported v	within 10 days of analysis		
Percent of results reported v	within 30 days of analysis		
Percent of results reported v	·		
Percent of results reported v	within 90 days of analysis		
	l signature:ed Samples put a number on the		
frozen samp	le		
out of temp	erature		
broken cont	ainer		
wrong prese	ervative		
other:			

WENT DESKE

Appendix G

Corrective Action Report for Microbiological Lab Audit Findings

Lab NO:	Audit date:	Lab Contact Name:							
Lab Name:		Phone Number:							
Non-conformities: (IDENT	IFY ERROR)		Is this a common occurrence?	Y/N					
Planned correction/remedial action: (HOW WAS MISTAKE RECTIFIED - This is not how to prevent reoccurrence of non-conformities)									
Do the non-conformities result in a need to implement corrective action? Y/N									
Planned Corrective action: (ACTIVITY THAT SHOULD BE IMPLEMENTED TO STOP THE RE-OCCURANCE OF NON-CONFORMITIES)									
Planned completed date	e: Com	pleted date:	Authorization Signature:						
				•					
Evidence for effectiveness: (What did lab do to verify that corrective action worked? i.e., checked Drinking Water Watch to see if result uploaded properly). List activity and date performed.									
This section filled out by D	WLCP CM								
CAR No.:	Date Received:								



Appendix H

Example of Microbiological Lab Chain of Custody Form

ACME Inc. Lab	o, 101 Roadrunner Ave	. Truth or Con	sequences, N	VM 879	01, 505	5-555-1234 email: acmela	ab@g	mail.com Lak	D ID # NM123	
Test Method: S	Lab Sample ID #:									
Water Supply S	WSS Code No. (5 digits): NM35###									
Chlorine Yes/N	Total:	Total:mg/l Compliance Sample: Yes or No								
	he " <u>Type</u> " of sample thout completely). Only					w and fill out the inform	ation	for your selection	n (all boxes	
1. Routine										
2 Papast	Sample Point ID:	Location:								
2. Repeat	Original Sample ID#									
3. GW	Source Facility ID#		Source Fac	Source Facility Name:						
Triggered			000.00.00	source rueme, rume.						
Source	Original Sample ID#				Sample Point ID# SP		1			
4 6144	Source Facility ID#		Source Fac	ility Na	mo:					
4. GW Repeat	, -		30urce rac	ility iva	iiie.	Consula Daint IDII CD				
кереас	Triggered Source Sam	ipie ib#				Sample Point ID# SP		1		
5. E-Coli	Facility ID#		Facility Na	me:						
Enumeration										
(LT2)	Turbidity (NTU)]							
6. Special	Facility ID#		Location:	Location:						
FIELD SAMPLE DATA & REMARKS			pH:	: Conductivity (µS/cm): Temp. (°C):						
Comments:				I						
			1							
Collected By:			Operator I	D#		Phone	e:			
	<u> </u>	Received By:								
Relinquished By:			Name (pri				Data			
Name (print) Date:			,,					Date: Time: (24 hr)		
Signature Time: Name (print) Date:			(24 hr) Signature Name (pri			<u> </u>	Date:			
Signature				Signa				Time: (24 hr)		
				(24 hr) Signat		•		als Intact: Yes/ No		
Ice Yes/ No:				Contract Con						
ice res/ No.										
Test Test Results										
		201		Volume Assayed: ml						
Start	Date: Tin		ie:		•			FC (D/A):		
					TC (P/A): EC (P/A):					
Finish Date: Tim		ne:		EC Enumeration: (per 100						
			ml)							
First A		Date:		Т						
			D-1							
Reviev			Date: Time:							



Appendix H

Example of Chemical Lab Chain of Custody Form

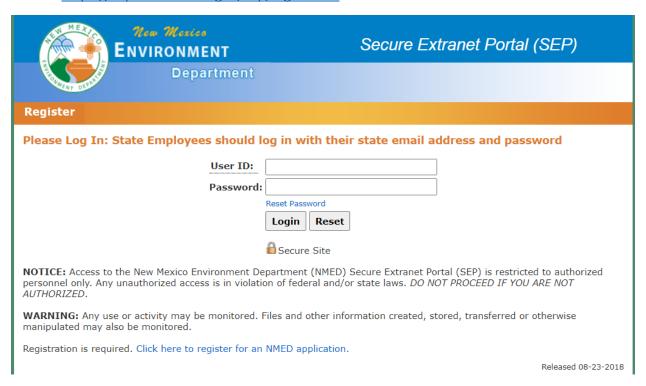
Chain of Custody Record					La	Lab Name:						
WSS Name:					_	Lab ID #						
WSS #:				_	Lab Address							
Phone Number:				$\overline{}$	Phone number: xxx-xxx-xxxx email:							
email:					$\overline{}$	ate:	Time	$\overline{}$				
	Packag	به ا	tandard Lev	el 4	1	oce.		$\overline{}$	Relinquised By Name (print)			
	itation:		MED DWLCP	E1 4	\dashv			_	gnature	iicj		
	ELAC [A2LA	_		_	$\overline{}$		$\overline{}$		n+1		
-		elivery (Ty			\dashv			_	Name (print) Signature			
Turn A	round T			ush	-	ate:	Time	Time: Recieved By				
			_Standard K	0311	100	ate:	IIIIIe	-	Name (print)			
	Name:				+			1-		it)		
Project					+	-		$\overline{}$	nature	•		
	Manag	er:			\dashv				Name (print)			
Sample					+				nature			
	er ID Nu					On Ice (Y/N): Custody Seal Intact(Y/N):						
	Numbe	r:			_	of cool			fcontair	nters:		
email:					_	ooler T						
Compl	iance Sa	mple (Y/I	N):		C	Chlorine (Y/N): Free: mg/LTotal: mg/L						
Date:	Time:	Matrix	Location	Sample #	рН	tem	η (μ	S/cm)	Analysi	is Method(s)/Pr	reservative	
							\perp					
							T					
							\top					
							\top					
							+					
							+					
							\top					
						\top	\dagger					
				 		+-	+					
Danie												
Remar	K5.											

Appendix I

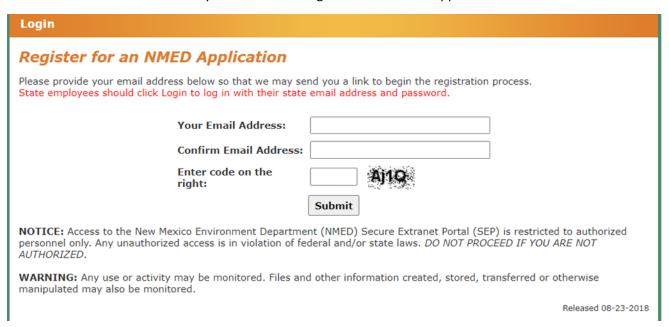


Instructions to Register for SDWIS LabToState

1. Go to https://sep.net.env.nm.gov/sep/login-form



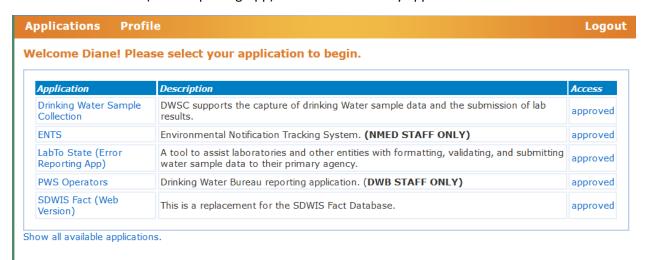
2. Click at the bottom where is says "Click here to register for an NMED application.



3. Follow the link in the email and fill out the registration form. The application you want to request is called LabToState.

Appendix I

- 4. To upload files log-in to SEP using your user ID and password.
- 5. Click on LabToState (Error Reporting App). It should be the only application that the lab has access to.



6. On the left-hand side of the screen click on Upload & Validate



- 7. Choose CSV as the file format. This is considered the lab's practice upload. It does not have to be real data. The date the lab does this successfully is the date for Appendix A part 8.
- 8. Browse to and select the file on your computer that you want to upload.
- 9. Type in your email address and click OK.

Appendix J



Corrective Action Response for PT Study Failure (Micro Labs Only)

Date:	
Person preparing response:	
PT Study#:	
Analysis/Method:	
Analyst:	
Description of failure:	
Data reviewed:	
Procedures reviewed:	
Operation of equipment checked (Y/N):	
Reason for failure:	
Corrective action taken:	



Appendix K

RTCR Sample Reporting and Notification (LabToState)

Total Coliform Routine Samples:

This section provides guidance to upload samples to SDWIS in situations where the results of a routine sample return as absent for total coliform.

- 1. Electronic compliance data <u>must</u> be submitted on either a *weekly*, or no greater than a bi-weekly basis, in the format specified by the Drinking Water Bureau (DWB), which is currently the Safe Drinking Water Information System (SDWIS). Only compliance data should be uploaded to SDWIS.
- 2. Submittals to SDWIS must include:
 - a. Water system name and ID#,
 - b. Date and time of sample collection,
 - c. Type of sample collected (routine, repeat, etc.),
 - d. Analysis results,
 - e. Chlorine residual measurement taken at the time of sample collection,
 - f. Facility ID#,
 - g. Sample collection point RT# and sample collection location address or sample point name
 - h. Sample collector's NM Operator/Sampler certification number as listed on the request form and name.
- 4. The completed Chain of Custody for each sample must be sent to the data team at NMMicroLabsCOC-LabResults@state.nm.us.
- 5. Laboratories must provide a copy of all sample results to the submitter/client within ten (10) working days from the completion of the analyses.

Total Coliform **Positive** Samples:

This section provides guidance to notify DWB and the water systems in situations where the results of a routine sample return as total coliform positive (total coliform present).

- 1. Total coliform positive samples are uploaded into SDWIS as stated above, but also must be reported directly to DWB and the water system.
- 2. Laboratories must notify DWB and the water system of any positive total coliform, fecal coliform, or E-coli analysis result(s) as soon as possible, but no later than 12 hours after identifying the result.
- 3. When a sample is determined to be positive for total coliform the lab will send an email to DWB via email address, nmenv.labsamples@state.nm.us under subject title: Total Coliform Positive Sample. This email will be directed to the RTCR Rule Administrator and Data Steward team, and their supervisors. The lab will attach the chain of custody or an electronic report which includes:
 - a. Water system name and ID#,
 - b. Analysis results,
 - c. Chlorine residual measurement taken at the time of sample collection,
 - d. Sample collection location name or address,

Appendix K

- e. Sample point ID number (RT#)
- f. Sample collection date and time, and
- g. Sample collector's name and phone#.
- 4. The RTCR Rule Administrator or his/her designee will provide a response to the lab stating the email was received.
- 5. The lab is also to provide notification to the submitting water system Administrative Contact (AC) by phone. If AC is unavailable or message cannot be left, attempt to contact the sampler listed on the COC should be made and noted.

Total Coliform Repeat Samples:

This section provides guidance in situations where the results of repeat samples return as total coliform positive following total coliform positive routine samples.

- 1. Following a compliance routine positive total coliform sample result(s), water systems will be required to collect repeat samples and possibly Groundwater Source Samples (GWS). Labs will email the chain of custodies for these samples or an electronic report to DWB via email address nmenv.labsamples@state.nm.us under subject title: Total Coliform Repeat Results. This email will be directed to the RTCR Rule Administrator and Data Steward teams, and their supervisors. The email notification will include an attached chain of custody or an electronic report which includes the following information:
 - a. Water system name and ID#,
 - b. Analysis results,
 - c. Chlorine residual measurement taken at the time of sample collection,
 - d. Sample collection point RP# and sample collection location address or sample point name,
 - e. Sample collection date and time,
 - f. Sample collector's name, phone#, and operator certification#
 - g. Original sampling point where positive sample was taken
 - h. Upstream,
 - i. Downstream, and
 - j. If required for compliance with the Ground Water Rule, a fourth sample (triggered source sample) will be taken at the source. The groundwater source sample must be identified by the DWBs designated facility identification number and location name (i.e. Well #1) and,
 - k. Original RT lab sample ID#.
 - 2. The RTCR Rule Administrator or his/her designee will provide a response to the lab stating the email was received.

NOTE: Laboratory must keep a written record of contacts made to report positive results, invalid results, or samples rejected by the laboratory. The record must contain information identifying the sample collector, who was contacted (name and affiliation), when the contact was made (date and time), and how the contact was made (in person, by phone, or by e-mail).

<u>NOTE</u>: These requirements are taken directly from the of New Mexico Statewide Price Agreement #80-667-18-27642, Microbiological Water Testing and the Drinking Water Laboratory Certification Program Guidance Manual. Failure to meet these requirements may lead to a downgrade of your laboratory certification or termination of the price agreement with DWB.

Appendix K

RTCR Reporting and Notification

Revision#0.0

September 21, 2021